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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,005	03/15/2004	William V. Judy	JUDY2	6823
1444	7590	10/19/2005	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			MALLARI, PATRICIA C	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/800,005	JUDY, WILLIAM V.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9, 10, 13 and 18 is/are rejected.
- 7) ☒ Claim(s) 5-8, 11, 12, 14-17 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The Office Action Summary of the action filed 10/4/05 erroneously states that the applicants have 2 months to respond. This copy of the Office action filed 10/4/05 is being sent to correct that response period to 3 months.

#### ***Information Disclosure Statement***

The information disclosure statement filed 7/19/04 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

#### ***Claim Objections***

Claims 2 and 13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 recites, "A device according to claim 1, wherein said bioimpedance measuring device comprises a plurality of measuring electrodes." However, claim 1, upon which claim 2 depends, recites "a bioimpedance measuring device, which at least comprises . . . at least two measuring electrodes". At least two electrodes is a plurality of electrodes. Therefore,

claim 2 fails to further limit the parent claim. Claim 13 similarly recites, "wherein a plurality of measuring electrodes is applied to said body", and claim 10, upon which claim 13 depends already recites, "applying . . . at least two . . . measuring electrodes to the body".

Claims 6 and 8 are objected to because of the following informalities:

on line 1 of claim 6, "said peak blood flow signal" should be replaced with "a peak blood flow signal" because the claim lacks sufficient antecedent basis for the limitation;

on line 1 of claim 8, "claim 1" should be replaced with "claim 5", lacks sufficient antecedent basis for the limitation "said peak blood flow" on line 2 of claim 8.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,417,715 to Noren et al. Claims 1 and 2 are rejected as being anticipated by US Patent No. 5,417,715 to Noren et al. Noren teaches a device comprising a bioimpedance measuring device, which device comprises at least two measuring electrodes 2, 3 and an impedance measuring device 11 for measuring an impedance signal Z between a pair of the electrodes 2, 3 (figs. 1 & 2; col. 5, lines 13-25 of Noren). Processing means 9 are able to determine a first time-derivative  $dZ/dt$  for the measured

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impedance signal Z, to separate from  $dZ/dt$  a peak signal PS that occurs after the beginning of diastole of the heart during a heart beat (col. 5, lines 32-41 of Noren), and to further determine a maximum value MAX of said peak signal PS (col. 5, lines 40-47; col. 6, lines 34-50 of Noren), wherein the maximum value determined is a maximum negative value of the signal.

As to the language in the preamble reciting, "for determining a peak blood flow signal of a blood flow through at least a section of a selected coronary artery of a beating heart of a mammal" on lines 1-3 of claim 1, the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art, since Noren teaches all of the claimed elements and their recited relationships. See *Ex parte Masham 2 USPQ 2<sup>nd</sup> 1647*. The device of Noren is certainly capable of being used to determine such a peak blood flow signal.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noren as applied to claims 1 and 2 above, and further in view of US Patent Application Publication No. 2003/0199955 to Struble et al. Noren lacks the measuring electrodes being arranged in a mesh. However Struble teaches pacemaker electrodes 50 being

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arranged in a mesh 18 for placement on the heart wherein such electrodes may be used to measure impedance (figs. 1 and 5; paragraphs 31, 35, 37, 43, 44, 87, and 88 of Struble). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the apparatus of Struble with the apparatus of Noren in order to impede the progression of dilated cardiomyopathy (paragraphs 7 and 36 of Struble).

Regarding claim 4, the electrodes are substantially equidistant (figs. 1 & 5 of Struble).

Regarding claim 9, the electrodes are capable of substantially covering a heart (figs. 1 & 5; paragraph 34 of Struble), wherein the size and shape required to cover the right and left ventricles of one person's heart may be of sufficient size and shape to cover the entirety of a second person's heart, particularly in a case where the first person is an adult male, and the second person is an infant.

Claims 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noren as applied to claims 1 and 2 above, and further in view of US Patent No. 5,305,745 to Zacouto et al. Noren teaches that the measuring electrodes are connected to the heart (fig 1; col. 4, lines 62-69 of Noren) but fails to state a specific place in or on the heart where the electrodes are placed. However, Zacouto teaches using a cardiac stimulator, wherein the measuring electrodes used to measure an impedance signal are placed in the coronary artery 9 (fig. 1; col. 27, line 46-col. 28, line 10 of Zacouto). Therefore, it would have been obvious to one of ordinary skill in the art

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at the time of invention to place the electrodes of Noren in the coronary artery, since Noren teaches a placing the measuring electrodes in the heart, and Zacouto describes the coronary artery as an appropriate site in or on the heart to place the electrodes. As to the language in the preamble of claim 10, the method disclosed by Noren in view of Zacouto is a method for determining a peak blood flow signal PF of blood flow through at least a section of at least one selected coronary artery of a beating heart of a mammal since the combined references recite all of the steps recited in claim 10. If the method disclosed by the combined references does not qualify as such a method, then the applicants have omitted an essential step of the method in claim 10 (i.e. a problem on under 35 U.S.C. 112, 2<sup>nd</sup> paragraph).

Regarding claim 18, the method is for determining peak blood flow signal of a blood flow through at least a section of substantially all major surface coronary arteries of the heart, wherein the electrodes are placed around such section (fig. 1 of Zacouto).

***Allowable Subject Matter***

Claims 5-8, 11, 12, 14-17, and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 5, 8, 12, and 15-17, the prior art of record fails to teach or fairly suggest a device or method wherein the processing means are able to determine a peak blood flow signal PF for said peak signal PS, by dividing the maximum value MAX

by the distance between those two of said at least two measuring electrodes between which the impedance signal  $Z$  was measured, when the device is being used, in combination with all of the other limitations of the claims.

Regarding claims 6, 7, and 14, the prior art of record fails to teach or fairly suggest a device comprising a bioimpedance measuring device further comprising scanning means which are able to select two or more pairs of the plurality of measuring electrodes during the heart beat, in combination with all of the other limitations of the claims.

Regarding claim 11, the prior art of record fails to teach or fairly suggest a method for determining a peak blood flow signal  $PF$  of a blood flow through at least a section of at least one selected coronary artery of a beating heart of a mammal, wherein a plurality of impedance signals  $Z$  are determined along a plurality of locations along the coronary artery, wherein, for each of the impedance signals  $Z$ , a first time derivative  $dZ/dt$  is determined, a peak signal  $PS$  is separated therefrom, and a maximum value  $MAX$  is determined from the peak signal  $PS$ .

Regarding claim 19, the prior art of record fails to teach or fairly suggest a method for determining a peak blood flow signal  $PF$  of a blood flow through at least a section of at least one selected coronary artery of a beating heart of a mammal, wherein at least the section of said at least one coronary artery is bounded by a pair of measuring electrodes of said at least two mutually spaced measuring electrodes, and wherein the electrodes cover the heart substantially completely, in combination with all of the other limitations of the claim.



### **Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,561,986 to Baura et al. describes determining a derivative of an impedance signal  $dZ/dt$  taken from the chest of a patient, wherein the O point is identified by finding the global maximum  $dZ/dt$  value in a peak signal PS occurring after the onset of diastole.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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